Remarks

Claims 162-187, 189-199, 201-229 and 231-239 are pending.

The specification has been amended to up-date the related applications.

In accordance with the discussions during the Examiner Interview, the independent claims 162, 192 and 209 have been amended to recite "wherein the composition has a dissolution of at least 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate." In view thereof, claims 188, 200 and 230 have been canceled without prejudice.

No issues of new matter should arise and entry of the amendment is respectfully requested.

Prior Art Rejection

Claims 162-239 are rejected under 35 USC § 103 as being obvious over Mughal et al (US Patent No. 4,524,060) in view of Boyer (US Patent No. 4,800,079) and further in view of Kerč et al (US Patent No. 6,042,847) or Klimesch et al (US Patent No. 5,073,379).

Applicants respectfully traverse the rejection and respectfully submit that one skilled in the art would not be motivated to combine Mughal, Boyer, Kerč, and Klimesch because they are directed to entirely different types of formulations. Mughal and Kerč are directed to sustained or controlled release formulations with the objective of releasing the drug over a period of 24 hours. Boyer and Klimesch, on the other hand, have relatively faster release rates when compared to Mughal and Kerč. A summary of Mughal, Boyer, Kerč, and Klimesch is set forth below.

Mughal	Boyer	Kerč	Klimesch
about 27% to about 70% of indoramin is release in 6 hours[1] from 87 to 96% of indoramin is released in 24 hours[2]	more than 65% of the fenofibrate is released from a galenical preparation in one hour[3]	67% to 87% nifedipine released in 16 hours[4] 100% of the drug is released in 24 hours[5]	100% of pseudoephedrine, propafenone, anipamil, vitamin B1, nicotinic acid, biperiden, and canthaxanthine released in 1 to 6 hours[6]
sustained release[7] composition	relatively fast release when compared to Mughal and Kerč	constant and controlled release composition[8]	relatively fast release when compared to Mughal and Kerč
capsule containing uncompressed pellets[9]	capsule containing uncompressed granules[10]	compressed tablet[11]	compressed tablet[12]

In view of the fact that the references are directed to different formulations having different release rates, one skilled in the art would not be motivated to combine references that teach sustained or controlled release formulations (e.g., Mughal, Kerč) with references that show formulations having a relatively faster release rate (e.g., Boyer, Klimesch). Moreover, one skilled in the art would not be motivated to combine references that teach capsules containing uncompressed granules (e.g., Mughal, Boyer) with references that teach compressed tablets (e.g., Kerč, Klimesch).

Additionally, Applicants respectfully submit that none of the cited references disclose or suggest the claimed composition having a dissolution of at least 75% in 30 minutes as measured

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[1] Mughal at Tables 1 and 2.
[2] Mughal at Tables 1 and 2.
[3] Boyer at column 3, line 40 to column 4, line 2; in a medium constituted by 118 ml N HCl and 84 ml solution of N NaOH distilled water: enough to obtain 1000.0 ml of medium, where the dissolution medium has a pH between 1.45 and 1.55.
[4] Kerč at Tables 1-3.
[5] Kerč at Tables 1-3.
[6] Klimesch at Table 1.
[7] Mughal at Abstract.
[8] Kerč at Abstract.
[9] Mughal at column 3, lines 50-62.
[10] Boyer at column 3, lines 13-15.
[11] Kerč at column 8, lines 53-67; Examples 1-8.
[12] Klimesch at Abstract; Examples.

using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or in a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

Mughal is directed to a sustained release formulation that releases about 27% to about 70% of indoramin in 6 hours,[13] and from 87 to 96% of indoramin in 24 hours[14] The presently claimed invention clearly has a dissolution profile that is significantly faster than the sustained release formulation described by Mughal.

In support of the fact that Boyer does not disclose or suggest the presently claimed dissolution profile, Applicants submit herewith a Declaration under 37 CFR § 1.132 by Philippe Réginault (hereafter the Réginault Declaration). The Réginault Declaration provides a comparison between the Boyer patent and the claimed invention.

It is known in the art that the composition described by Boyer is represented by Lipanthyl® 250. *See* Réginault Declaration at ¶ 7. The composition recited in the claims is represented in the specification at Example 2 and by Lipanthyl® Supra. *See* Réginault Declaration at ¶ 8. A comparison of the dissolution profile of Boyer (i.e., Lipanthyl® 250) and the claimed invention (i.e., Lipanthyl® Supra) is shown in Tables 1 and 2 and Figures 1 and 2 in the Réginault Declaration at ¶ 11.

For the Examiner's convenience, the results described in the Réginault Declaration and shown in Example 2 and Figure 1 in the present application are reproduced in the Table below.

Time	% Dissolution recited in Pending Claims	% Dissolution of Lipanthyl® 250 corresponding to Boyer	% Dissolution of Lipanthyl® Supra corresponding to the Invention	% Dissolution of Inventive Example 2 in the Application
30 minutes	at least 75%	1.9%	89.8%	95.9%

[13] Mughal at Tables 1 and 2.
[14] Mughal at Tables 1 and 2.

In comparing Boyer and the claimed invention, the Réginault Declaration, at ¶ 12, states:

> The results shown above clearly demonstrate that Lipanthyl® 250 (i.e., U.S. Patent No. 4,800,079 to Boyer) and Lipanthyl® Supra (i.e., the above-identified application) have very different dissolution profiles — both for the extent and for the rate. Lipanthyl® Supra presented a complete dissolution of fenofibrate within 1 hour whereas Lipanthyl® 250 only released 4% fenofibrate (i.e., 10 mg) within 1 hour. Hence, the two formulations have a significantly different dissolution profiles.

Based on the results shown in the Réginault Declaration and the specification at Example 2, Applicants respectfully submit that the presently claimed invention has an unexpectedly superior dissolution profile when compared to Boyer. Accordingly, one skilled in the art would not arrive at the claimed invention based on the teachings in Boyer.

Applicants respectfully submit that Kerč and Klimesch do not cure the deficiencies of Mughal or Boyer. Kerč teaches away from the presently claimed invention because Kerč teaches a three-phase pharmaceutical formulation with controlled release properties.

In view of the above, Applicants respectfully submit that the presently claimed invention is unobvious over the cited references and respectfully request that the rejection under § 103 be withdrawn.

Information Disclosure Statement

Applicants respectfully request that the PTO review and consider the Information Disclosure Statement, PTO-1449 Form and the attached references, including the Declaration under 37 CFR § 1.132 by Pascale Blouquin.

The Declaration under 37 CFR § 1.132 by Pascale Blouquin (the Blouquin Declaration) shows that the presently claimed invention has unexpectedly superior properties when compared to the dissolution data in the Laboratory Notebooks submitted with the Blouquin Declaration. Blouquin Declaration at ¶ 14. A comparison of the pending claims, the inventive example in the present application and the dissolution data from Lot No. 2177 in the Laboratory Notebook No. 1 at Bates Number Fournier 1001569 is set forth in the table below. Blouquin Declaration at ¶ 14.

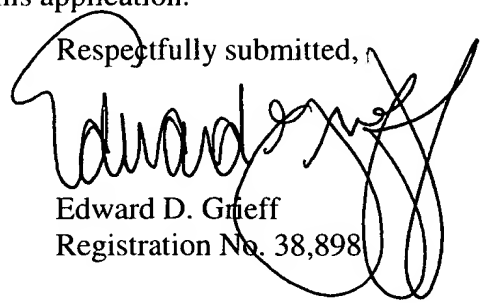
Time	% Dissolution Recited in Pending Claims	% Dissolution by Inventive Example shown in Example 2 of the Application	% Dissolution by Curtet as Lipanthyl® 200M from Lot No. 2177 described in the First Blouquin Declaration and shown in Lab Notebook No. 1 at Fournier No. 1001569	% Dissolution by Curtet as Lipanthyl® 200M from Lot No. 2177 described in Example 2 of the Application
30 minutes	at least 75%	95.9%	67.7%	54.9%
60 minutes	--	--	78%	--

The claimed invention requires at least 75% dissolution in 30 minutes. The data in the Laboratory Notebook submitted in the Information Disclosure Statement herewith shows that it takes 60 minutes for Curtet's Lipanthyl® 200M to achieve a dissolution of 78%. Blouquin Declaration at ¶ 15. In other words, it takes almost twice as long for Curtet's Lipanthyl® 200M to achieve a dissolution that the claimed fenofibrate composition can achieve in 30 minutes. Blouquin Declaration at ¶ 15. In view of these results, it is Ms. Blouquin's opinion that the claimed invention is superior to Curtet's Lipanthyl® 200M. Blouquin Declaration at ¶ 15.

Conclusion

An early and favorable reconsideration and allowance of claims 162-187, 189-199, 201-229 and 231-239 is respectfully requested. Examiner Sheikh is encouraged to contact the undersigned to expedite prosecution of this application.

Respectfully submitted,



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